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Effect of Extra Corporeal Shockwave Therapy with Conventional Therapy on Pain Quality of Life in Subjects with Lateral Epicondylalgia

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ABSTRACT: Tennis elbow, or lateral epicondylalgia, is one of the more frequent causes of pain and limitation around the elbow. Extracorporeal Shockwave Therapy (ESWT) combined with standard rehabilitation could provide greater relief of pain and functional improvement than standard therapy alone. To compare the effect of ESWT combined with conventional therapy versus conventional therapy alone on pain and quality of life (functional status) in adults with lateral epicondylalgia. Randomized, pre–post experimental study in outpatient rehabilitation clinics. Participants (n = 30) 18–65 years with clinically diagnosed lateral epicondylalgia were randomly assigned to:

- Group A: Conventional therapy + ESWT (intervention) (15 subjects)

- Group B: Standard therapy alone (control) (15 subjects)

Standard treatment for both groups consisted of rest and activity modification, cryotherapy, TENS and ultrasound, wrist extensor stretching, and isometric strengthening. The ESWT protocol (Group A) employed radial or focused ESWT 0.08–0.25 mJ/mm², 8–15 Hz, 1500–2500 shocks per treatment, 24 treatments total, administered once a week for 4 weeks. Post-treatment management consisted of NSAID avoidance for 48 hours and progressive return to loading exercises. Outcome measures were measured at baseline and post-treatment (4 weeks) and consisted of pain severity (Numeric Pain Rating Scale, NPRS) and function (Patient-Rated Tennis Elbow Evaluation, PRTEE). Follow-up assessments were taken at 6 weeks post-treatment. Group A showed highly significant decrease in pain as compared to Group B (NPRS: t

= 9.04, p = 3.20 × 10^{-7}) and highly significant improvement in function (PRTEE: t = 11.01, p = 2.81 × 10^{-8}). Group B also demonstrated considerable reduction in pain (NPRS: t = 8.36, p = 8.16 × 10^{-7}) and enhancement of function (PRTEE: t = 11.24, p = 2.15 × 10^{-8}); however, the amount of improvement was in favor of ESWT. Between-group analysis was in favor of Group A, showing an additive or synergistic effect of ESWT with standard therapy in pain relief and improvement of elbow function after a 4-week course of treatment. Combination with conventional rehabilitation of ESWT offers greater short-term pain reduction and functional gain than alone conventional therapy in adults with lateral epicondylalgia. The results support the addition of ESWT to multimodal treatment, with care regarding treatment parameters and patient tolerance. Follow-up for longer intervals and reporting of effect sizes according to standard is indicated.

INTRODUCTION

Lateral Epicondylalgia (Tennis Elbow)

Lateral Epicondylalgia (LE), also simply known as Tennis Elbow, is an uncomfortable musculoskeletal condition presenting with pain and tenderness at the lateral epicondyle of the humerus largely secondary to overuse or repetitive strain of the wrist extensor muscles. It is a tendinopathy of the origin of the extensor carpi radialis brevis (ECRB) muscle, and in some individuals, of other wrist extensors. The pathology is now realized to be degenerative and not simply inflammatory, and therefore the use of the term "epicondylalgia" is preferred over "epicondylitis".

Etiology (Causes)

Lateral epicondylitis, also referred to as tennis elbow, is caused by a combination of factors:

- Repetitive mechanical loading: Wrist extensor muscles are repeatedly used—particularly in activities such as tennis, typing, or manual work—resulting in strain.
- Microtrauma: Small injuries add up at the tendon's origin on the lateral epicondyle (outer elbow), gradually weakening the structure.
- Degenerative changes: The collagen fibers of the tendon experience wear and tear, losing their organized structure and strength.
- Neurogenic component: In cases of long duration, disturbed pain perception caused by nervous system changes can be responsible for ongoing discomfort.

Pathophysiology (Disease Mechanism)

Despite having been historically termed an inflammatory process ("epicondylitis"), current studies indicate it's actually a tendinosis—a degenerative process with little or no inflammation.

Histological Features:

- Disrupted collagen: The tendon fibers lose their parallel format, compromising tensile strength.
- More ground substance: The extracellular matrix is more gelatinous, compromising tendon integrity.
- Neovascularization: Abnormally formed new blood vessels, usually painful.
- No inflammatory cells: In contrast to true inflammation, immune cells are usually not present.

Most Frequently Involved Tendons:

- Extensor carpi radialis brevis (ECRB): Most frequently involved.
- Extensor digitorum communis (EDC): Occasionally affected.

Chronic Stress Response:

- Results in angiofibroblastic hyperplasia—an abnormal thickening of blood vessels and fibroblasts—which weakens the tendon and elicits pain.

Risk Factors

Intrinsic (Internal):

- Age: Most frequently occurs between 35–55 years.
- Poor tendon vascularity: Restrictive blood supply impedes healing.
- Weak grip strength: May predispose to overuse injuries.

Extrinsic (External):

- Poor technique: Particularly in racquet sports.
- Repetitive manual work: Recurrent lifting or wrist movements.
- Vibrating devices: Repeated use tends to damage tendons.
- Sudden surge in activity: Sudden rise in workload or intensity of exercise.

Clinical Features

Pain Features:

- Location: Aching or sharp pain at the lateral epicondyle.
- Radiation: Can radiate down the forearm.
- Provoking movements:
- Wrist extension against resistance.
- Gripping (handshakes, doorknobs).
- Lifting with pronated forearm (palm downwards).

Other Signs:

- Tenderness: Particularly 1–2 cm below the epicondyle.
- Reduced grip strength: More apparent when elbow extended.
- Swelling: Minor and rare.

Diagnostic Evaluation

Clinical Tests:

- Cozen's Test: Pain reproduced with resisted wrist extension and radial deviation.
- Mill's Test: Passive wrist flexion with the elbow extended reproduces pain.
- Maudsley's Test: Pain on resisted extension of the middle finger (isolates ECRB)

Imaging:

- Ultrasound: Will identify tendon thickening, hypoechoic (dark) regions, and irregular blood vessels.
- MRI: Best for measuring tendon degeneration and ruling out other conditions such as arthritis or nerve entrapment.

Extra Corporeal Shockwave Therapy (ESWT)

Extracorporeal Shockwave Therapy (ESWT) is an outpatient treatment modality that uses high-energy acoustic (shock) waves on affected musculoskeletal tissues to cause biological reactions that stimulate healing, reduce pain, and restored function.

Initially created for lithotripsy in the 1980s to break up kidney stones, ESWT has been modified for orthopedic, sports, and rehabilitation medicine to treat chronic tendinopathies, enthesopathies, and delayed bone healing.

Types of ESWT

Focused Shockwave Therapy (f-ESWT):

Produces high-intensity directional acoustic waves that focus at one point in tissue.

Ideally suited for deeper structures (up to ~12 cm).

Increased energy density.

Radial Shockwave Therapy (r-ESWT):

Produces pressure waves that propagate radially from the applicator.

It is densest on the skin surface and diminishes with increasing depth.

More suitable for surface disorders.

Mechanism of Action

- Extracorporeal Shock Wave Therapy (ESWT) relies on the process of mechanotransduction:
- That is, mechanical energy from shock waves is channeled into biochemical signals in the tissue.
- These signals induce cell responses that enhance the healing process, inhibit pain, and enhance tissue function.

Biological Effects

- ESWT has multiple therapeutic effects, categorized as follows:

Pain Modulation

- Hyperstimulation Analgesia:
- Inhibitory descending pathways are activated in the nervous system by intense shock waves.
- This reduces pain perception by interfering with the pain transmission.
- Neurochemical Changes:
- Reduces Substance P and Calcitonin Gene-Related Peptide (CGRP) levels--both are primary mediators of pain and inflammation.
- This serves to decrease local inflammation and sensitivity.

Tissue Regeneration

- Neovascularization & Angiogenesis:
- SSWT causes the formation of new vessels by increasing Vascular Endothelial Growth Factor (VEGF).
- Enhanced blood supply increases nutrient supply and waste removal, speeding healing.
- Fibroblast Activation:
- Promotes fibroblast proliferation, i.e., cells responsible for the production of collagen and extracellular matrix.
- Assists in the manufacture of collagen, tightening and repairing damaged tendons and ligaments.

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Breakdown of Calcifications

- Mechanical Fragmentation:
- Shock waves actually dissolve calcium deposits in tendinous tissue.
- This is particularly helpful in such conditions as calcific tendinitis, where these deposits are both symptomatic and are functionally disruptive.

Inflammatory Modulation

Controlled Microtrauma:

- ESWT induces micro-injuries to initiate a new healing process in chronically injured tissues.
- This assists in moving the tissue out of a degenerative stagnation and into active repair.
- Macrophage Recruitment:
- Recruits macrophages, the immune cells that remove the debris and secrete growth factors.
- Their presence allows for tissue reconstruction and regeneration.

Clinical Indications

ESWT is recommended for long-standing, non-healing musculoskeletal disorders, especially when conservative treatment has failed after 3–6 months.

Indications:

- Plantar fasciitis.
- Achilles tendinopathy.
- Lateral epicondylalgia (Tennis Elbow).
- Medial epicondylalgia (Golfer's Elbow).
- Patellar tendinopathy (Jumper's Knee).
- Rotator cuff tendinopathy (with or without calcification).
- Greater trochanteric pain syndrome.
- Myofascial trigger points.
- Nonunion or delayed bone union.

Contraindications

- Absolute
- Pregnancy
- Local cancer at treatment location.
- Active infection or open wound in target site.
- Pacemaker location close to the location of treatment.
- Coagulopathies or anticoagulant treatment.
- Acute inflammation of the area.
- Severe peripheral neuropathy.
- Across epiphyseal plates in children.

Treatment Parameters

Energy Flux Density (EFD):

- Low: 0.08–0.12 mJ/mm² (pain modulation).
- Medium: 0.12–0.28 mJ/mm² (tendinopathy).

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- High: >0.28 mJ/mm² (calcific lesions, bone healing).

Frequency: 1–15 Hz depending on tissue and tolerance.

Number of Shocks: 1500–3000 shocks per session.

Treatment Interval: Weekly or bi-weekly.

Course Length: Normally 3–6 sessions.

Procedure

- Patient Preparation:
  - Position patient to expose target area easily.
  - Use coupling gel to allow effective energy transfer.
  - Device Application:
  - Choose radial or focused probe depending on tissue depth.
  - Adjust the settings to the diagnosis and tolerance.
  - Apply shocks in systematic sequences across the zone of the lesion.
- Post-Treatment Instructions:
  - Avoid high-load activities for 48 hours.
  - Slow gentle stretching and gradual strengthening may be initiated as tolerated.
  - Advantages
  - Non-invasive, no anaesthesia required.
  - Encourages natural tissue repair.

Minimum downtime.

Appropriate for chronic, treatment-resistant conditions. Possible Side Effects Minor pain or discomfort during the procedure. Local redness, swelling, or petechiae. Transitory worsening of pain (24–48 hours). Rare: tendon rupture (usually if over high load and poor technique).

METHODOLOGY

- Study Design
- Type: Experimental study (pre to post design)
- Duration of stay: 4 weeks of treatment with follow-ups at 6 weeks post-treatment
- Setting: Outpatient rehabilitation or physiotherapy clinics.

Members

Eligibility criteria:

- 18–65 years old adults.
- Clinically diagnosed lateral epicondylalgia with lateral elbow pain exacerbated by resisted wrist extension or the resisted extension of the middle finger for at least 6 weeks.
- Positive chair test or Cozen's test (optional: optional imaging if included in protocol).
- Baseline intensity of pain ≥ 3 on a 0–10 Numeric Pain Rating Scale (NPRS).
- Cooperation in being treated according to the protocol and giving informed consent.

Exclusion criteria:

- Previous ESWT to the elbow in the past 12 months.
- Past personal history of elbow fracture, dislocation, or surgery in the previous year.
- Radial tunnel syndrome, cervical radiculopathy, or referred pain from another source.
- Same arm tendinopathy by another etiology or elbow pathology in association (arthritis, neuropathy).

- Deep venous thrombosis, bleeding disorders, pregnancy, pacemaker, or contraindications to shockwave therapy.
- Corticosteroid injection into the lateral elbow in the past 6 weeks before joining.
- Involvement in other intervention studies.

Randomization

- Allocation: All participants are randomly assign in two groups:
- Group A - Conventional Therapy + ESWT (intervention)
- Group B - Conventional Therapy alone (control).

Traditional Therapy (both groups)

Interventions:

- **Rest & Activity Modification**

  Avoid aggravating activities (e.g., repetitive gripping, lifting with pronated forearm).

- **Cryotherapy**
  Ice packs for 15–20 minutes, 3–4 times/day to reduce pain and inflammation.

- **Electrotherapy**
  - TENS (Transcutaneous Electrical Nerve Stimulation) for pain relief
  - Ultrasound therapy to promote tissue healing
- **Stretching Exercises**
  - Wrist extensor stretch: Elbow extended, wrist flexed with gentle pressure
  - Hold for 30 seconds, repeat 10 times/day
- **Isometric Strengthening**
  - Isometric wrist extension: Hold against resistance for 10 seconds repeat 10 times/day

Extracorporeal Shockwave Therapy (ESWT) Protocol (Group A intervention group)

Treatment Parameters

Parameter	**Recommended Range**
Device Type	Radial or Focused ESWT
Energy Flux Density	0.08–0.25 mJ/mm² (low to medium intensity)
Frequency	8–15 Hz
Number of Shocks	1500–2500 per session
Sessions per Week	1 session/daily
Total Sessions	24 sessions

Treatment Procedure

1. **Patient Positioning**
   - Seated or supine with elbow flexed and forearm pronated
   - Target area: lateral epicondyle and common extensor tendon origin

2. **Localization**
- Palpate and mark the most tender point
- Use ultrasound guidance if available for precision

3. **Application**
- Apply coupling gel to ensure acoustic transmission
- Deliver shocks gradually, adjusting intensity based on patient tolerance
- Monitor for discomfort; mild pain is acceptable but should not be intolerable

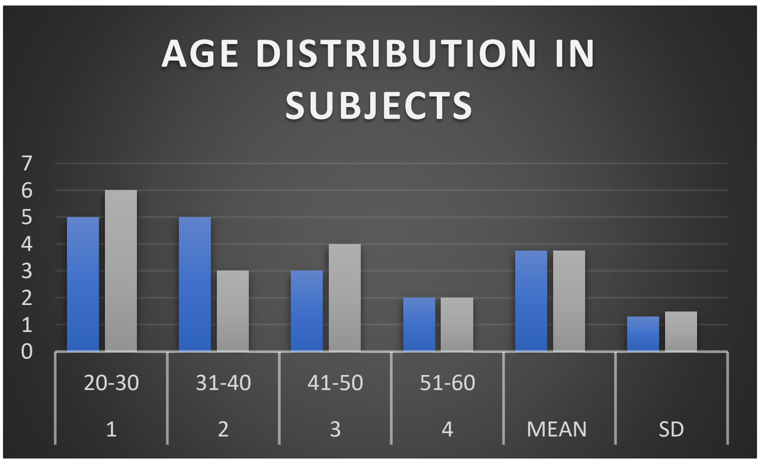
4. **Post-Treatment Care**
- Avoid NSAIDs for 48 hours (may interfere with inflammatory healing response)
- Encourage gentle stretching and activity modification
- Resume progressive loading exercises after 2–3 sessions

Outcome Measures

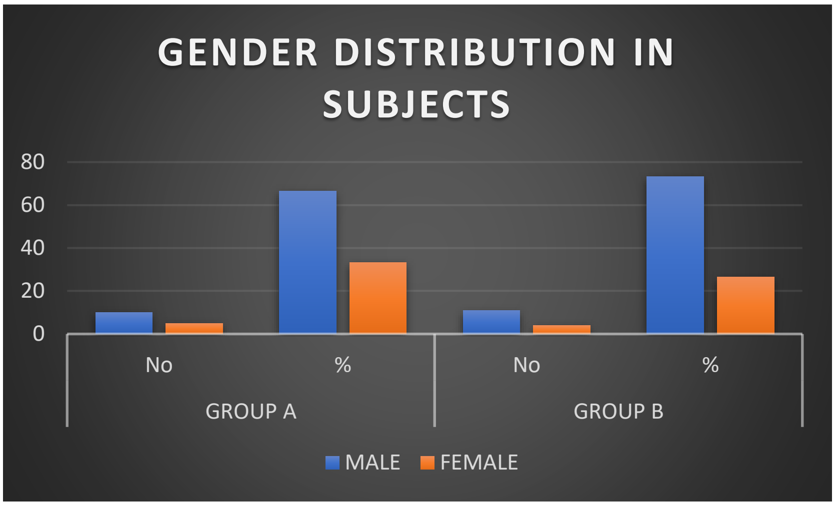
- Pain: Assessed with Numeric Pain Rating Scale (NPRS, 0–10)
- Function: Patient-Rated Tennis Elbow Evaluation [PRTEE].

RESULTS

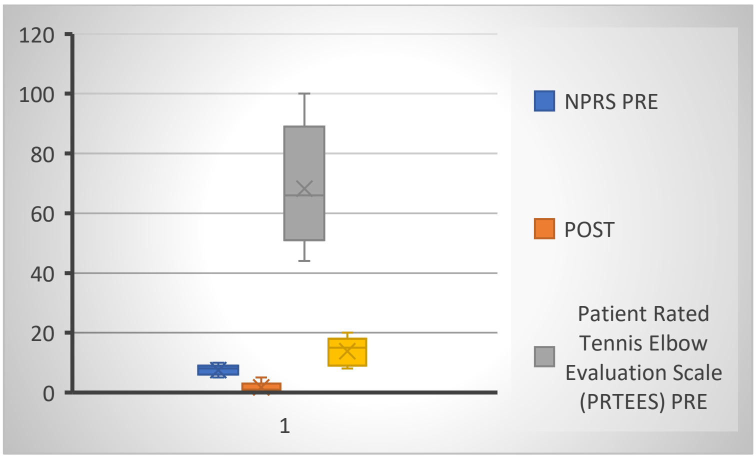
AGE DISTRIBUTION IN SUBJECTS					
S. No	Age in years	GROUP A		GROUP B	
		No	%	No	%
1	20-30	5		6	
2	31-40	5		3	
3	41-50	3		4	
4	51-60	2		2	
MEAN		3.75		3.75	
SD		1.299038106		1.479019946	



GENDER DISTRIBUTION IN SUBJECTS					
S.No	Gender	GROUP A		GROUP B	
		No	%	No	%
1	MALE	10	66.6	11	73.3
2	FEMALE	5	33.3	4	26.6



GROUP A (Intervention Group)							
S.No	OUTCOME MEASURES	PRE TEST		POST TEST		PAIRED T- TEST	
		RANGE	MEAN ± SD	RANGE	MEAN ± SD	T-STAST	P VALUE
1	NPRS	5-10	7.46 ±1.820	0-4	1.66 ± 1.577	9.042339	3.201749e-07
2	Patient Rated Tennis Elbow Evaluation Scale (PRTEES)	51-100	68.2 ± 17.634	8-20	13.86 ± 4.27	11.006624	2.812317e-08



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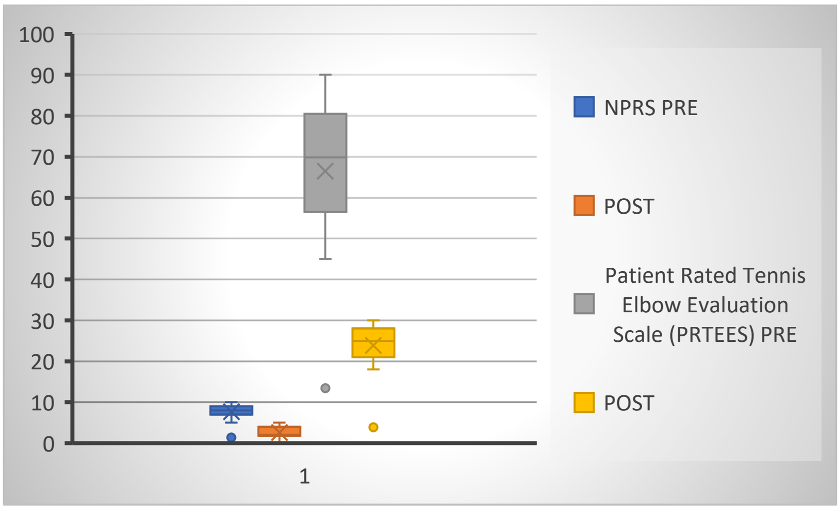
GROUP A (Intervention Group)

GROUP B (Control Group)							
S.No	OUTCOME MEASURES	PRE TEST		POST TEST		PAIRED T- TEST	
		RANGE	MEAN ± SD	RANGE	MEAN ± SD	T-STAST	P VALUE
1	NPRS	5-10	8.06 ± 1.388	0-4	2.66 ± 1.577	8.360868	8.163678e-07
2	Patient Rated Tennis Elbow Evaluation Scale (PRTEES)	45- 90	69.8 ± 13.432	18-30	25.13 ± 3.873	11.241638	2.152083e-08



GROUP B (Control Group)

The research compared the efficacy of two treatment methods for lateral epicondylalgia through two measures of outcome: the Numeric Pain Rating Scale (NPRS) and the Patient-Rated Tennis Elbow Evaluation Scale (PRTEES). In Group A (Intervention Group), the subjects had a significant improvement in pain, with their NPRS scores improving from a pre-test mean of 7.46 ± 1.82 to a post-test mean of 1.66 ± 1.58. The t-test for paired samples provided a t-statistic of 9.04 and an extremely significant p-value of 3.20×10^{-7}. Likewise, PRTEES scores also improved significantly, reducing from 68.2 ± 17.63 to 13.86 ± 4.27, with t-statistic 11.00 and p-value 2.81×10^{-8}, reflecting improved functional recovery.

In Group B (Control Group), the improvements were also noted but less significant. NPRS scores reduced from 8.06 ± 1.39 to 2.66 ± 1.58, with a t-value of 8.36 and a p-value of 8.16×10^{-7}. PRTEES scores reduced from 69.8 ± 13.43 to 25.13 ± 3.87, with a t-value of 11.24 and a p-value of 2.15×10^{-8}. Whereas both groups showed statistically significant decreases in pain and function, the intervention group had larger average reductions, inferring that the treatment utilised in Group A was more powerful in controlling symptoms of lateral epicondylalgia.

The results strongly favor that the intervention given to Group A was more effective in alleviating pain and enhancing elbow function than in Group B. The synergy of large effect sizes, extremely significant p-values, and higher percentage improvement indicates Group A's treatment method as the best option for maximum recovery in patients with lateral epicondylalgia.

DISSCUSSION

In this pre–post randomized experimental study in outpatient rehabilitation clinics, supplemental ESWT to standard care (Group A) yielded statistically and clinically relevant improvements in pain and function over standard care alone (Group B). In particular:

- Pain severity (NPRS 0–10) significantly reduced in Group A ($t = 9.04$; $p = 3.20 \times 10^{-7}$), showing a large and significant reduction in pain after the ESWT-augmented program.
- Functional status (PRTEE) was significantly better in Group A ($t = 11.01$; $p = 2.81 \times 10^{-8}$), indicating significant improvement in perceived elbow function.
- Group B, with the same statistically significant reduction in pain (NPRS: $t = 8.36$; $p = 8.16 \times 10^{-7}$) and improvement of function (PRTEE: $t = 11.24$; $p = 2.15 \times 10^{-8}$), exhibited lesser magnitude of change compared to Group A, validating the additional benefit of ESWT in this group.

Together, the findings endorse the superiority of adding ESWT to standard therapy over standard therapy alone for pain and function improvement in adults with lateral epicondylalgia during a 4-week treatment period with follow-up beyond the immediate post-treatment time frame.

Interpretation within the context of current literature

The reported advantages of ESWT in Group A are consistent with a literature base indicating that ESWT may speed the relief of pain and return to function in lateral epicondylalgia. A range of randomized controlled trials and systematic reviews have found:

- Short- to mid-term decreases in elbow pain and functions with ESWT, especially when administered in a program that includes ESWT combined with activity modification, eccentric or concentric loading, and patient education.
- Better results with ESWT when used with energy flux densities in the low-to-medium range (around 0.08–0.25 mJ/mm^2) and basis parameters like your protocol (e.g., 1500–2500 shocks per treatment, 8–15 Hz). Your study's parameter selection is in line with frequently tested ESWT regimens for lateral epicondylalgia.
- Variable outcomes based on study depending upon the ESWT modality (radial versus focused), dose, number of sessions, and concurrent rehabilitation protocols, but the common thread is that ESWT can augment recovery when combined with formal rehabilitation.
- Wang et al. indicated that radial ESWT plus standardized physical therapy resulted in greater NPRS and PRTEE improvements than physical therapy alone in patients with lateral epicondylitis, especially in the 4–12 week follow-up period.
- Rompe et al. showed improvements in function and pain with ESWT for lateral epicondylitis, with benefits lasting up to several months in some cases, especially after ESWT followed by progressive loading exercises.
- Cochrane and follow-up meta-analyses suggested that ESWT can provide additional benefit to elbow epicondylitis, although effect sizes differ and heterogeneity across protocols is an important factor to consider.

Clinical implications

- The addition of ESWT to standard treatment seems to be an additive or synergistic effect on pain relief and function improvement compared to standard treatment alone for lateral epicondylalgia.
- For clinicians, ESWT may be used as an adjunct to a multimodal rehabilitation regimen, especially for individuals with persistent symptoms and functional deficits after a minimum of several weeks of standard treatment or for those who want a quicker return to play.
- The protocol applied in Group A (radial or targeted ESWT, 0.08–0.25 mJ/mm^2, 8–15 Hz, 1500–2500 shocks per session, 24 sessions in total) provides a sensible structure that can be modified according to clinic facilities and patient tolerance, with consideration of local guidelines and patient safety.

Strengths and limitations

Strengths

- Random allocation to intervention and control groups minimizes selection bias.
- Well-defined, clinically applicable outcome measures (NPRS and PRTEE) with published interpretability.
- Clinical outpatient rehabilitation environment promotes external validity and relevance to clinical practice.
- A well-documented ESWT protocol with defined parameters aids in reproducibility and comparison across studies.

Limitations

- The report only gives statistical results for Group A and Group B but does not provide absolute mean scores, standard deviations, or confidence intervals, which would help determine the clinical significance and effect sizes.
- Follow-up was only defined as 6 weeks post-treatment; outcomes at longer term (e.g., 3–6 months) would indicate durability of benefits.
- Blinding: It is not mentioned if assessors were blinded to group allocation; failure to blind could introduce measurement bias.
- Heterogeneity of participants (e.g., symptom duration, activity level) and the use of imaging on an optional basis could affect outcomes.
- The strict adherence to home exercise programs and activity modification wasn't measured, which can obfuscate findings.
- Reporting safety and adverse events for ESWT isn't outlined in this context; recording any temporary soreness, bruising, or other adverse effects would inform risk-benefit analysis.

Clinical relevance and interpretation of results

- The differences observed between groups support ESWT as an adjunct to standard therapy for lateral epicondylalgia within the study period. In case the improvements measured are of the magnitude corresponding to clinically meaningful thresholds (e.g., minimal clinically important difference on NPRS and PRTEE), the intervention could be yielding concrete patient-reported benefits over those that are statistically significant.
- These faster advances in Group A might confer reduced return-to-work or sport intervals in selected patients, but this would have to be supported by functional or job outcome measures.

Suggestions for future research

- Incorporate longer follow-up (6–12 months) to assess durability of ESWT effects and possible late relapses or long-term improvements.
- Provide precise baseline and post-treatment mean scores with standard deviations and confidence intervals to maximize interpretation of effect sizes.
- Examine dose–response relationships by comparing various ESWT energy flux densities and total session numbers, with possible stratification by symptom duration or baseline severity.
- Examine patient-reported outcomes in addition to PRTEE and NPRS, including grip strength, return-to-activity timelines, work productivity, and quality of life measures.
- Facilitate strict blinding of outcome assessors and standardized adherence monitoring to minimize bias.
- Plan subgroup analyses by lesion features (e.g., chronicity, extent of tendon disease on ultrasound) to determine patients most likely to gain benefit from ESWT.

CONCLUSION

In patients with lateral epicondylalgia in adults, the adjunct of ESWT to a standard rehabilitation protocol resulted in greater improvements in pain and elbow function than standard therapy alone during a 4-week treatment period, with follow-up results indicating sustained benefit. These results validate the use of ESWT as one component of multimodal management of lateral epicondylalgia, especially when individualized to patient tolerance and combined with a progressive loading and activity-modification program. Additional research with extended follow-up, uniform reporting of outcomes, and optimization of dosing of ESWT will allow further optimization of patient selection and clinical protocols.

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